To: Lowit, Anna[Lowit.Anna@epa.gov]; Odenkirchen, Edward[Odenkirchen.Edward@epa.gov]
From: Waleko, Garland
Sent: Mon 4/24/2017 6:58:47 PM
Subject: RE: Draft Response re: Acute dermal waiving

Sounds good – Ed with your blessing I will send this on

From: Lowit, Anna
Sent: Monday, April 24, 2017 2:56 PM
To: Waleko, Garland <Waleko.Garland@epa.gov>; Odenkirchen, Edward <Odenkirchen.Edward@epa.gov>
Subject: RE: Draft Response re: Acute dermal waiving

Let's keep this simple

Ex. 5 - Deliberative Process

Anna B. Lowit, Ph.D.

Senior Science Advisor

Immediate Office

Office of Pesticide Programs, USEPA

w: 703-308-4135

c: 703-258-4209

From: Waleko, Garland
Sent: Monday, April 24, 2017 2:52 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Odenkirchen, Edward <Odenkirchen.Edward@epa.gov>
Subject: Draft Response re: Acute dermal waiving

Hi Ed and Anna, it's been a while since we talked (my fault that I dropped this!) but how does this simplified answer look (highlighted):

Ex. 5 - Deliberative Process

Ex. 5 - Deliberative Process

-----Original Message-----
From: Kate Willett [mailto:kwillett@humanesociety.org]
Sent: Thursday, February 23, 2017 5:12 PM
To: Waleko, Garland <Waleko.Garland@epa.gov>
Cc: Troy Seidle <tseidle@hsi.org>; Victoria Katrinak <vkatrinak@humanesociety.org>; Lowit, Anna <Lowit.Anna@epa.gov>
Subject: RE: Acute dermal waiving

Great, thanks for the quick response Garland, and we will eagerly await the results of your discussions.

Best,

Kate

-----Original Message-----

From: Waleko, Garland [mailto:Waleko.Garland@epa.gov]

Sent: Thursday, February 23, 2017 5:09 PM

To: Kate Willett <kwillett@humanesociety.org>

Cc: Troy Seidle <tseidle@hsi.org>; Victoria Katrinak <vkatrinak@humanesociety.org>; Lowit, Anna <Lowit.Anna@epa.gov>

Subject: RE: Acute dermal waiving

Hi Kate, actually we are discussing this with EFED next week, something we've had to reschedule a few times, so we haven't forgotten - we will get back to you soon.

Thanks for the reminder

Garland

-----Original Message-----

From: Kate Willett [mailto:kwillett@humanesociety.org]

Sent: Thursday, February 23, 2017 5:03 PM

To: Waleko, Garland <Waleko.Garland@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>

Cc: Troy Seidle <tseidle@hsi.org>; Victoria Katrinak <vkatrinak@humanesociety.org>

Subject: RE: Acute dermal waiving

Dear Anna and Garland:

We haven't heard from you regarding the questions below so am sending this as a reminder.

Hope the new year is finding you well!

Best,

Kate

-----Original Message-----

From: Kate Willett

Sent: Monday, December 12, 2016 8:25 PM

To: Waleko, Garland <Waleko.Garland@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>

Cc: Seidle Troy <troy.seidle@me.com>; Victoria Katrinak <vkatrinak@humanesociety.org>

Subject: RE: Acute dermal waiving

Dear Anna and Garland,

Thank you so much for taking the time to talk to us last Thursday and for reaching out to your colleagues in EFED to provide insight into their decision-making process. The information provided was very helpful in pointing to some immediate steps forward and future work to be done.

We were very pleased to have confirmed EPA's strong commitment to NICEATM's proposed roadmap to implementation of alternative methods, and excited to hear the level of coordination between OPP and OPPT on uptake of acute methods and other projects. It is good to know that the promise for strong synergy between the two divisions is in the process of being realized.

We appreciate that there are two primary issues to resolved before OPP would consider cytotoxicity approaches for identifying non-toxic chemicals. The first is EPA's classification categories III (>500<5000 mg/kg; caution, no symbol, harmful if swallowed) and IV (>5000 mg/kg; caution or no signal word required, no symbol, no hazard statement required or registrant may choose to use Category III statement) vs. GHS categories 4 (> 300 < 2000 mg/kg; Warning: Exclamation point in diamond, harmful if swallowed), Category 5 (>2000 < 5000 mg/kg; Warning: No symbol, May be harmful if swallowed) and not classified (> 5000 mg/kg), and whether EPA could abide by identification of "non-toxic" substances as >2000 mg/kg. The second is that the cytotoxicity methods have not been tested against a wide range of pesticides and are therefore not ready for consideration by OPP. We can further investigate ways of addressing these issues.

The discussion with Anita and Edward was enlightening in that what is most important for EFED assessments is to increase certainty in species-to-species extrapolations in particular with respect to endangered species. There is a project at OECD to characterize species differences with respect to sensitivity to endocrine disrupters; there may be opportunity for building on this project, along with other modeling efforts within ORD, to begin to address EFED's needs. We look forward to exploring these options in the future.

We do have a couple of questions regarding issues that came up during the discussion:

- It was interesting to hear from EFED that they don't actually use dermal acute data in their assessments. Would this allow OPP to reconsider whether they would accept oral to dermal acute bridging for ingredients as well as formulations as the preponderance of data suggest possible?

- We understand that EFED is in the process of revising their assessment procedures to align with recommendations form the 2013 NAS report; is there an opportunity to be involved in this process?

Thanks again for your time, and look forward to your responses.

Best,

Kate

P.S. Anna I hope you are feeling much better!!

Catherine Willett, PhD

Director, Regulatory Toxicology, Risk Assessment and Alternatives The Humane Society of the United States Humane Society International Washington, DC and Boston, MA
kwillett@humanesociety.org t +01.240.599.6785 c +01.617.271.3194

-----Original Message-----

From: Waleko, Garland [mailto:Waleko.Garland@epa.gov]

Sent: Friday, December 02, 2016 08:44

To: Kate Willett; Lowit, Anna

Cc: Seidle Troy

Subject: RE: Acute dermal waiving

Hi Kate, we'll add this as a topic to discuss on our call next week, if that sounds good to you. We'll expand the invite to include some EFED folks.

Thanks,

Garland

-----Original Message-----

From: Kate Willett [mailto:kwillett@humanesociety.org]

Sent: Thursday, December 01, 2016 5:04 PM

To: Lowit, Anna <Lowit.Anna@epa.gov>; Waleko, Garland <Waleko.Garland@epa.gov>

Cc: Seidle Troy <troy.seidle@me.com>

Subject: Acute dermal waiving

Dear Anna, Garland:

I'd like to follow-up briefly on the acute dermal waiving issue following the call yesterday. First, huge congratulations and thanks for finalizing the guidance for waiving acute dermal testing for formulations – that is a very large step in a positive direction! And it's clear you have been working very hard to address these issues this year.

Second, I'd like to further discuss the dermal waiving of ingredients and EFED issue. After a brief review of the ESA as well as EPA's 2004 document "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency: Endangered and Threatened Species Effects Determinations," it seems that there is not a direct legislative mandate that specifies OPP's participation in providing certain types of information for protecting "off –target" species (threatened or otherwise) – in other words, it seems as though there is flexibility for EPA to determine not only how it interprets its role but also what information it uses to provide protection for these species.

EFED's data requirements for protecting endangered species, as currently interpreted and implemented, pose significant impediments to adoption of alternative approaches – not only in the case of acute dermal lethality but in other areas such as fish acute toxicity. In that light, it would be helpful to understand the process EFED uses to determine which information it uses to estimate protective exposure limits during its risk assessment process, and to perhaps open a discussion regarding how EFED might incorporate new types of information while maintaining the same level of protection, as other offices within OPP are doing.

With the goal of addressing the impediments, could you please help us understand:

· The legislative mandate (or interpretation thereof) for EFED's contribution to protection of endangered species

· The actual EFED requirements for acute dermal LD50 for addressing threatened or endangered species

Any light you could shed on these points would be extremely helpful and much appreciated.

Thanks, and best regards,

Kate

Catherine Willett

Director, Regulatory Toxicology, Risk Assessment and Alternatives The Humane Society of the United States Humane Society International Washington, DC and Boston, USA

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